REMARKS

Restriction Requirement

The Examiner, in the Restriction Requirement, required election of one of the following groups of claims:

Group I, claims 1-7, 11-21, 29 and 30 drawn to a method for generating an immune response against a bacteria by mucosally administering a gene delivery vehicle, class 424, subclass 234.1;

Group II, claims 1-5, 8-21, 29 and 30, drawn to a method for generating an immune response against a virus by mucosally administering a gene delivery vehicle, class 424, subclass 204.1;

Group III, claims 1-5, 11-24, 29 and 30, drawn to a method for generating an immune response against an antigen by mucosally administering a gene delivery vehicle and a second gene delivery vehicle encoding a second antigen, class 424, subclass 184,1; and

Group IV, claims 1-5, 11-21, 25-30, drawn to a method of generating an immune response by mucosally administering a gene delivery vehicle and a polypeptide, class 424, subclass 184.1 and class 514, subclass 2.

Applicants hereby elect to prosecute the claims of Group II, claims 1-5, 8-21, 29 and 30, **with traverse**.

Applicants traverse on the ground that the above Restriction Requirement is unduly burdensome and in error. MPEP §803 states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions. (Emphasis added.)

The claims of Groups I, II, III and IV are all directed to methods as set forth in independent claim 1, namely methods of generating an immune response an antigen by mucosally administering a replication-defective gene delivery vehicle that includes a sequence encoding the antigen. All pending claims depend directly or ultimately from claim 1. Thus, the particular antigen encoded by the gene delivery vehicle is a matter of choice and, as such, does not in any way affect the search conducted regarding these claims. Indeed, a single search for references related to the generation of immune response following delivery of a replication-defective gene delivery vehicle as set forth in claim 1 will necessarily find art related to all four allegedly distinct groups of claims, particularly in light of the fact that all groups share the same class (class 424). Moreover, Applicants query how claims 1-5, 11-21, 29 and 30, which are

found in each allegedly distinct group of claims, can be patentably distinct from themselves and, in addition, how a search for references relevant to these claims can fail to reveal art relevant to the other groups.

Thus, Applicants submit that an examination of the claims of Groups I-IV as one group would not impose a serious burden on the Examiner. In fact, Applicants believe that failure to examine the claims as proposed would pose a far greater burden on the Patent and Trademark Office, by requiring a duplication of effort and resources, since a search directed to claims in Groups I through IV would **necessarily** turn up relevant references, if such references exist. Additionally, imposing a four-way Restriction Requirement will cause a considerable expense to Applicants. Accordingly, Applicants respectfully traverse the above Restriction Requirement and request reconsideration thereof.

Election of Species Requirement

The Examiner, in the Election Requirement, required election of one species of groups (d) to (h), if Group II is elected. In addition, election of one of species (i) to (l), one of (m) and (n) and, finally, one of (x) to (z).

As a threshold matter, Applicants request that the election of species requirement be clarified. For example, the election requirement as between viral vectors lists retroviral or adenoviral vectors but fails to give adenoassociated viral vectors, picornaviral vectors, alphaviral, vaccinia vectors, etc. Thus, the Election of species requirement fails to adequately set forth and define the allegedly distinct species. Accordingly, Applicants request clarification.

Nonetheless, in order to comply with the requirement to elect a single species, Applicants provisionally elect, **with traverse**, the following:

HIV (species (d)), which reads on claims 1-5 and 8-30;

viral vector (species (j)), which reads on claims 1-30;

alphaviral vectors, which read on claims 1-30; and

Class I and/or class II MHC proteins, which read on claims 1-30.

As noted above, Applicants traverse on the grounds that the election of species requirement is not adequately set forth. The Office has not delineated the differences between the allegedly distinct species encompassed by these claims and, accordingly, Applicants cannot be required to elect a single species.

Applicants also traverse on the grounds that it would not unduly burdensome to search all allegedly distinct species together. Indeed, a search of the art for methods of generating an immune response to any selected antigen by mucosally administering a replication-defective gene delivery vehicle comprising a sequence encoding the selected antigen would necessarily

reveal art relevant to each and every recited antigen, each and every delivery vehicle and each and every immune protein because, in **each and every** case, the components used in must result in generation of immune response following mucosal administration. In view of the specific claim language, it is not required that each element of the various dependent claims be individually searched. Therefore, because searching would be entirely routine and in **no** way burdensome, Applicants submit that the election of species requirement is improper and should be withdrawn entirely.

Finally, it is to be understood that the election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to any nonelected subject matter during the pendency of this application.

Respectfully submitted,

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